DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

Food and Drug Administration
Rockville MD 20857

SEP 3 3 2000

Peter S. Reichertz, Esquire
Arent, Fox, Kintner, Plotkin & Kahn
1050 Connecticut Avenue, NW
Washington, DC 20036-5339

Re: Docket No. 78N-036L
Comment Nos. CP20, LET182

Dear Mr. Reichertz:

This is in reference to the citizen petition dated June 9, 1995, submitted on behalf of the C. B. Fleet Company, Inc., and filed in FDA's Dockets Management Branch as Comment No. CP20 under Docket No. 78N-036L. The petition requested amendment of the tentative final monograph for OTC laxative drug products (50 FR 2124) to allow for use of a large volume tap water enema as the final cleansing step, in lieu of a bisacodyl suppository or enema, in bowel cleansing systems. The petition included 23 literature references in support of the request.

The Division of OTC Drug Products responded to your petition in a letter dated December 13, 1999 (Comment No. LET182 under Docket No. 78N-036L). In that letter, we requested that you submit the following:

1. Data demonstrating how much water is safe for administration in a tap water enema, including demographic and medical information about the populations studied.

2. Data to demonstrate how much water is needed for a tap water enema with your client's kit(s) and the diagnostic procedures for which the volume(s) are appropriate.

3. Any new data that may be available for the kits, either from cliical trials, literature or safety databases.

4. The rationale for selection and timing of the ingredients used in the kits.

5. The total number of kits that have been sold since the product was first marketed, and all adverse reports received regarding the kits.

6. All adverse reports for the enema bag, whether it was sold alone or as part of a kit.

7. Consumer and professional warnings and directions for your client's kits (including use of the enema bag) that will assure us that these products are adequately labeled and safe for the t target population.

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8. Any data or other information you have to support where and by whom the tap water enema should be administered.

9. Samples of the complete kits as they are currently marketed (including all consumer and professional labeling and other information that may be available for use with the kits).

It is now over 9 months since we requested the information/data, and you have not provided us with a response.

We are unable to approve your client's petition without the subject data. Accordingly, if we do not receive the requested data/information within 4 weeks from the date of this letter, we will complete the petition process utilizing only the information submitted to date and we will deny the petition without prejudice to a future filing when the data/information become available.

If you have any questions regarding the above or if we can be of any assistance, please contact Mary Robinson at 301-827-2222.

Sincerely yours,

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research